Your research is FDA-regulated if it involves the evaluation of a test article* in one or more humans

*A drug/biologic:

(A) *articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and*

(B) *articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and*

(C) *articles (other than food) intended to affect the structure or any function of the body of man or other animals; and*

(D) *articles intended for use as a component of any article specified in clause (A), (B), or (C).* (FD&C Act)

*A device:

means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

1) *recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,*

2) *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*

3) *intended to affect the structure or any function of the body of man or other animals, and*

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (FD&C Act)

Note: FDA regulations also apply to the use of human specimens (even if de-identified) used to evaluate the safety or effectiveness of a device

If YES, then:
21 CFR 50 (Protection of Human Subjects) and
21 CFR 56 (Institutional Review Boards)
ALWAYS APPLY.
More determinations are needed!

For drugs, is an IND application to FDA needed, requiring additional compliance with 21 CFR 312?

For devices, is an IDE application to FDA needed, requiring additional compliance with 21 CFR 812? (If FDA has already made the determination, IRB doesn't have to make it!)

YES, if the test article is never-before-FDA approved drug or biologic

NO: If the test article is an FDA-approved, marketed, drug, and, ALL OF THE FOLLOWING criteria are met:

- The drug product is lawfully marketed in the United States,
- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug,
- In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug,
- The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product,
- The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).
- The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).

See https://www.fda.gov/media/79386/download for other examples of IND exempt activities including bioavailability or bioequivalence Studies in Humans, radioactive or cold isotopes, cancer studies etc.

No, if the device is "IDE-Exempt" (§812.2(c)). Most likely for UConn:
-Studies of an already cleared medical device…
…used/investigated in accordance with the indications in the cleared labeling.
-Diagnostic device studies (e.g., in vitro diagnostic studies) are exempt as long as the sponsor complies with the requirements at 21 CFR 809.10(c) for labeling, and if the testing:
--is noninvasive;
--does not require an invasive sampling procedure that presents significant risk;
--does not by design or intention introduce energy into a subject; **and**
--is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically establish diagnostic product or procedure.

Yes, if the IRB determines the device to be Significant Risk:

-Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
-Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
-Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
-Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

No, if the IRB determines the device to be Non-Significant Risk (not SR, not IDE-exempt)

- Abbreviated IDE requirements must be met (§812.2 (b))
- IRB approval of an NSR device study serves as the IDE approval